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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,059	10/25/2001	Craig Basson	955-12	9868

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/027,059	Applicant(s) Basson
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 25, 2001* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-69* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-69 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 1-8 are drawn to a polypeptide fragment classified in Class 530, subclass 300+.

Group 2. Claims 9-22 are drawn to a polynucleotide encoding the fragment of Group 1, an expression vector and host cell, classified in Class 536, subclass 23.1, Class 435, subclasses 69.1, 252.3.

3. It is noted that the claims of the instant application have been determined to include linking claims The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 23, 28, 30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to

examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 3-19. Claims 23-24, 32 are drawn to a method of inhibiting cell proliferation comprising introducing a polypeptide into the cell, *ex vivo* wherein the polypeptide is introduced, wherein the cell is not malignant, wherein the cell is one of the 16 tissues claimed in claim 30, each of which is a separate and distinct invention classified in Class 435, subclass 4, Class 514, subclass 2+. Applicant is required to elect a single invention. Claims 26, 27, 30, 34 will be examined as they are drawn to the elected invention.

Group 20-35. Claims 23-24, 33 are drawn to a method of inhibiting cell proliferation comprising introducing a polypeptide into the cell, *in vivo* wherein the polypeptide is introduced, wherein the cell is not malignant, wherein the cell is one of the 16 tissues claimed in claim 30, each of which is a separate and distinct invention classified in Class 435, subclass 4, Class 514, subclass 2+. Applicant is required to elect a single invention. Claims 26, 27, 30, 34 will be examined as they are drawn to the elected invention.

Group 36-45. Claims 23-24, 28-29, 31-32 are drawn to a method of inhibiting cell proliferation comprising introducing a polypeptide into the cell, *ex vivo* wherein the polypeptide is introduced, wherein the cell is malignant, wherein the malignant cell is one of the 9 malignant cell types claimed in claim 29, each of which is a separate and distinct invention classified in Class 435, subclass 4, Class 514, subclass 2+. Applicant is required to elect a single invention. Claims 26, 27, 31, 34 will be examined as they are drawn to the elected invention.

Group 46-54. Claims 23-24, 28-29, 31, 33 are drawn to a method of inhibiting cell proliferation comprising introducing a polypeptide into the cell, *in vivo* wherein the polypeptide is introduced, wherein the cell is malignant, wherein the malignant cell is one of the 9 malignant cell types claimed in claim 29, each of which is a separate and distinct invention classified in Class 435, subclass 4, Class 514, subclass 2+. Applicant is required to elect a single invention. Claims 26, 27, 31, 34 will be examined as they are drawn to the elected invention.

Group 55. Claims 35- 43 are drawn to a method for identifying drug candidates classified in Class 435, subclasses 4, 6, 7.1.

4. It is noted that the claims of the instant application have been determined to include linking claims The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 44, 55 drawn to a method of stimulating growth of heart cells comprising contacting the heart cells with an antagonist of 5/T-box sequence of the TBX5 gene. Upon the allowance of the

linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 56. Claims 44-47, 48, 53, 55 are drawn to a method of stimulating the growth of heart cells comprising contacting the heart cells with an antagonist of the 5/T-box sequence of the TBX5 gene wherein the antagonist is an antisense construct wherein the growth is stimulated *ex vivo*, classified in Class 536, subclass 23.1, Class 514, subclass 44.

Group 57. Claims 44-47, 48, 53-55 are drawn to a method of stimulating the growth of heart cells comprising contacting the heart cells with an antagonist of the 5/T-box sequence of the TBX5 gene wherein the antagonist is an antisense construct wherein the growth is stimulated *in vivo*, wherein the patient has suffered a heart attack, classified in Class 536, subclass 23.1, Class 514, subclass 44.

Group 58. Claims 44-48, 53-55 are drawn to a method of stimulating the growth of heart cells comprising contacting the heart cells with an antagonist of the 5/T-box sequence of the TBX5 gene wherein the antagonist is an antisense construct wherein the growth is stimulated *in vivo*, wherein the patient is affected by cardiomyopathy, classified in Class 536, subclass 23.1, Class 514, subclass 44.

Group 59. Claims 55-57 are drawn to a method of stimulating the growth of heart cells comprising contacting the heart cells with an antagonist of the 5/T-box sequence of the TBX5 gene wherein the antagonist is a peptide antagonist, classified in Class 514, subclass 2+.

Group 60. Claims 58-62 are drawn to a method of identifying drug candidates that stimulate heart cells comprising determining whether compounds bind to TBX5, classified in Class 435, subclass 4.

Group 61. Claims 63-67 are drawn to a method of identifying drug candidates that stimulate heart cells comprising determining whether compounds act as antagonists of 5'T-box sequence of the TBX gene, classified in Class 435, subclass 6.

Group 62. Claims 63-67 are drawn to a method of identifying drug candidates that stimulate heart cells comprising determining whether compounds act as antagonists of amino acids encoded by 5'T-box sequence of the TBX gene, classified in Class 435, subclass 7.1.

Group 63. Claims 68-69 are drawn to a monoclonal antibody, classified in Class 530, subclass 350+.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions 1, 2, 63 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 3-62 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1 and 3-55, 59, 60, , 62 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as an antigen for the production of antibodies.

The inventions of Groups 2 and 55-58, 60-61 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polynucleotide product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 63 and 3-62 are not at all related because the antibody of Group 63 is not recited in any of the methods of Groups 3-62.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Groups 56-58 are further subject to election of a single disclosed species.

Claim 44 is generic to a plurality of disclosed patentably distinct species comprising heart cells with different structures and functions wherein the heart cells are (a) myocytes (claim 46), (b) fibroblasts (claim 47), (c) endothelial cells (claim 47, (d) cardiac stem cells (claim 47).

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

(703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
March 24, 2003